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(54) **PHARMACEUTICAL COMPOSITION
CONTAINING PIRFENIDONE IN
SUSTAINED-RELEASE TABLET FORM**

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See application file for complete search history.

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(57) **ABSTRACT**

The instant invention relates to a process for the preparation of a pharmaceutical composition in sustained-release tablet form comprising from 600 milligrams to 2400 milligrams of Pirfenidone (PFD), in such a way that the drug is bioavailable during an extended period of time of 12 hours from its administration. In this way, the anti-fibrotic and anti-inflammatory action of the drug Pirfenidone is optimized. Moreover, the instant invention offers advantages and a higher therapeutic efficacy compared to other pharmaceutical forms of Pirfenidone for oral administration and its therapeutic application in the regression of chronic renal failure secondary to primary glomerulosclerosis; it shows a better activity with regard to the reduction and/or regression of deleterious effects in breast capsular contracture observed after the surgical implantation of breast implants in humans and has an important anti-TNF- α and anti-TGF- β 1 action for the treatment of hepatic fibrosis.

1 Claim, 6 Drawing Sheets